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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,216	04/18/2002	Hugo Seinfeld	HUBR-1204	8458

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FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER	
ASHEN, JON BENJAMIN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/049,216	Applicant(s) SEINFELD, HUGO	
	Examiner Jon B. Ashen	Art Unit 1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 September 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☒ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *15 and 19-37*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of 3. NOTE: The proposed claim amendment would raise new issues that would require consideration under 35 U.S.C. § 112 2nd paragraph in regards to the metes and bounds of the text "of symptoms" as added to claims 15, 19 and 21 and would require a new search of pharmaceutical compositions as now recited in amended claim 19, at least. Additionally, the proposed claim amendment, if entered, would raise the issue of new matter as "xenophobic" which appears in amended claim 21 is not supported by the disclosure of the specification as filed. Moreover, no support for the terminology "once per recurrence of symptoms" could be located in the instant disclosure nor has Applicant indicated where support for either "xenophobic" or "once per recurrence of symptoms" may be found in the specification as filed.

Continuation of 11. does NOT place the application in condition for allowance because:

Applicants amendments to the claims have overcome the outstanding rejections under 35 U.S.C. § 112 2nd paragraph. However, the inclusion of the terminology, "of symptoms" in claims 15, 19 and 21 is considered grounds for a new rejection under 35 U.S.C. § 112 2nd paragraph because the metes and bounds "of symptoms" cannot be determined without assumption. Additionally, the metes and bounds of a "xenophobic" oligoribonucleotide or polyribonucleotide cannot be determined.

Applicants amendment of claims 29-31, to delete the term "directly", is sufficient to overcome the outstanding rejection under 35 U.S.C. § 112 1st paragraph: new matter.

Applicant has asserted (pg. 5, 2nd and 3rd paragraphs), with regard to the outstanding rejection under 35 U.S.C. § 112 1st paragraph, of claims 15, 19, 20 and 21-37 for being drawn to a broad genus of methods of treatment, that the claimed methods of treatment and presented example provides sufficient written description of the claimed invention. However, this assertion is not persuasive for the reasons set forth in the Action mailed 6/14/2005, section 11, which (briefly reiterated herein) considers that no adequate written description is provided of xenogeneic oligo- and or polyribonucleotides that will function to a provide treatment of any infection caused by any member of the Herpesviridae and/or any skin tumor because the specification does not provide the specific structure of any particular xenogeneic oligo- and or polyribonucleotides that are required to practice the method that would correspond with the function of providing treatment of any infection caused by any member of the Herpesviridae and/or any skin tumor nor has Applicant provided any distinguishing identifying characteristics of the broad genus of methods as claimed.

Applicant has argued, in regards to the outsanding rejection of claims 15, 20, 21, 23, 27, 29, 31-32 and 36, under 35 U.S.C. § 102(b) over Draper, that this prior art reference does not teach or suggest the use of natural RNAs (pgs 5 and 6). However this argument is not persuasive because the limitation of "natural RNA" is not limitation that appears in the instant claims and ribozymes produced by genetic engineering methods are disclosed as obtainable from a unicellular organism, as claimed. Applicants also argues that the cited reference does not disclose how recurrences typically found in herpes infections can be avoided and that the active agent is applied only once single time per occurrence of the disease. However, this argument is not persuasive and is confusing as the claimed invention does not specifiy a method of avoiding recurrences nor claim that the active agent is applied only one single time per occurrence of the disease. This argument appears to address limitations that are not in the claims.

Applicant has argued, in regards to the outstanding rejection of claims 15, 20, 21, 23, 27, 29, 31-32 and 36, under 35 U.S.C. § 102(b) over Dirheimer, that Dirheimer discloses tRNA which also contains DNA and is used in an aqueous medium above all and must be applied daily or every other day and that the possibility of avoiding recurrence is not disclosed but that the presently claimed invention prevents recurrences and must be used in water free medium and need not be administered daily or even every other day but may be administered only once per recurrence (pg. 6). However, these arguments are not persuasive becasuse the claimed invention is a method comprising, which does not exclude the administration of DNA and because, as set forth in the Action mailed 6/14/05, Dirheimer discloses the dissolution of the tRNA in sesame oil which is considered to read on the administration of anhydrous preparations because sesame oil is an anhydrous preparation, not an aqueous medium as asserted by Applicant. Additionally, the method of Dirheimer et al. is a method of treatment of an animal in need thereof and is therefore an inherent disclosure of a method wherein xenogeneic oligo and/or polyribonucleotides are administered once per recurrence as each recurrence would indicate that the animal was in need thereof. The outstanding rejection over Dirheimer is maintained, in particular in light of the 112 2nd paragraph issue identified above in regards to "of symptoms", as presently presented, there is no requirement for whatever symptoms are recurring to be symptoms related to Herpesviridae infection and/or skin tumors.

Applicants arguments that evidence of patentability is provided by issued claims in a European patent (pg. 6) is not persuasive because the instant filing is an Application for a US Patent and determination of patentability is made under US law and practice.